

Early Versus Delayed Closure of Covering Ileostomy after Low Anterior Resection for Ectal Carcinoma

Original Article

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ABSTRACT

Background: This study aimed to assess the outcomes of low anterior resection (LAR) for rectal cancer, comparing early versus delayed loop ileostomy closure. Morbidity, mortality, and quality of life scores throughout a 12-month postoperative period were the main emphasis.

Patients and Methods: Between January 2023 and 2024, 32 patients with rectal cancer who had treatment at Menoufia University Hospital with LAR and temporary covering ileostomy participated in a prospective clinical research. Early closure (14 days postsurgery) and delayed closure (2 months postsurgery) were the two equal groups into which the patients were randomly assigned. Operative details, postoperative complications, and quality of life assessments at 2, 6, and 12 months following surgery were among the important characteristics assessed.

Results: A total of 15 out of 32 patients were excluded from the study due to anastomotic leak, unstable medical state, or loss to follow-up. The two groups did not differ significantly in terms of surgical data, complications, or baseline characteristics. However, these differences were not statistically significant ($P=0.094$, $P=0.071$, $P=0.462$). At 2, 6, and 12 months postoperatively, the early closure group's quality-of-life (QoL) scores were slightly higher than those of the delayed closure group (mean scores: 102.13 vs. 96.81, 107 vs. 102.5, and 109.56 vs. 108.19, respectively). Factors including age, sex, comorbidities, type of surgery, and timing of closure did not significantly correlate with QoL outcomes at 12 months, according to linear regression analysis.

Conclusion: When compared with delayed closure, early loop closure had no discernible impact on postoperative QoL in patients undergoing LAR for rectal cancer, ileostomy. The incidence of complications and operative results were comparable for both closure techniques. To validate these findings, more research with larger sample sizes is required.

Key Words: Early closure, Delayed closure, Loop ileostomy, Low anterior resection, Morbidity, Mortality, Postoperative outcomes, Quality of life, Rectal cancer.

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INTRODUCTION

Colorectal cancer marks the third commonest cancer overall and the second leading cause of cancer-related deaths worldwide. Rectal cancer is one of its kind that presents the most difficulties because of its anatomical position and the technical requirements for surgical care. Patients with rectal cancer now have better oncological results and sphincter preservation rates thanks to the development of low anterior resection (LAR) combined with complete mesorectal excision. However, the risk of anastomotic leaking remains a significant concern and often necessitates the development of a short-term loop ileostomy to safeguard the anastomosis and promote appropriate recovery^[1].

Temporary ileostomies, while effective in mitigating the impact of anastomotic complications, introduce their own

set of challenges, including stoma-related complications such as skin irritation, dehydration, and electrolyte imbalances. Furthermore, because of the physical and mental strain of having a stoma, patients frequently have a lower quality of life (QoL). The timing of ileostomy closure, whether early (within 2–4 weeks) or delayed (8–12 weeks or later), is a critical factor influencing both clinical outcomes and patient satisfaction^[2].

Early ileostomy closure proponents contend that it enhances patients' general QoL and shortens the length of stoma-related problems. Early closure may improve recovery since it has been linked to fewer stoma-related problems and a speedier return of intestinal continuity. However, its broad use has been constrained by worries about postoperative complications and insufficient anastomotic healing^[3].

Conversely, delayed closure provides more time for anastomotic healing and recovery from the primary surgery, which may reduce the risk of postoperative complications. Nevertheless, this approach can prolong the period of stoma-related morbidity and negatively affect patients' psychological well-being and healthcare costs. The trade-offs between early and delayed closure remain a topic of ongoing debate, as current evidence from clinical trials and observational studies has yet to yield a definitive recommendation^[4].

QoL has emerged as a key consideration in evaluating the outcomes of surgical interventions for rectal cancer patients. Living with a stoma can significantly impact physical, emotional, and social aspects of life, underscoring the importance of assessing QoL in studies comparing early and delayed ileostomy closure. Standardized tools, such as the EORTC QLQ-C30, provide reliable and validated measures to capture patients' perspectives on their postoperative recovery and overall well-being. By incorporating QoL assessments, clinicians can better understand the broader implications of ileostomy closure timing on patients' lives^[5].

This study presents the results of a randomized trial comparing early versus delayed closure of covering ileostomy following LAR in patients with rectal cancer.

PATIENTS AND METHODS:

Methods

Study design

A total of 32 patients with rectal cancer who underwent LAR and had a covering ileostomy made at Menoufia University Hospital between January 2023 and 2024 were included in this prospective clinical study.

Inclusion criteria

Adults with a diagnosis of rectal cancer who underwent low or ultralow anterior rectum resection with the establishment of a temporary covering ileostomy as part of curative treatment and who were at least 18 years old were eligible to participate.

Exclusion criteria

Patients who were judged incompetent for surgery, refused surgery, or had incurable rectal cancer because of local invasion or metastases were not included.

Postoperative follow-up

Vital signs, bowel function regain, nutritional condition, and development of early problems like infection, ileus, or anastomotic leaks were all extensively examined after surgery for each patient.

Group allocation

Cases were stratified into two groups upon the timing of ileostomy closure:

- Early closure group: On the 14th postoperative day, ileostomy closure was carried out. To evaluate anastomotic integrity and rule out leakage, patients had a computed tomography scan using a water-soluble contrast agent before closure.
- Late closure group: It was not until the second postoperative month that the ileostomy was closed. To assess the anastomosis, a second antegrade contrast-enhanced computed tomography scan was carried out via the stoma prior to closure.

Surgical procedure

General anesthesia was used for the ileostomy closure procedure. An oval incision encircled the mucocutaneous junction. The stoma was removed from the rectus sheath and peritoneal cavity using both blunt and sharp dissection (Figure 1). Transverse continuous or interrupted sutures were used to close the loop ileostomy, and a second layer of sutures was placed over the anastomosis site for reinforcement (Figure 2). Continuous sutures were used to approximate the rectus sheath, and inverted absorbable sutures were used to close the subcutaneous tissue. Interrupted vertical mattress nonabsorbable sutures were used for skin closure, allowing gaps between stitches to permit seroma drainage.



Figure 1: Delivery of ileal loops before closure.

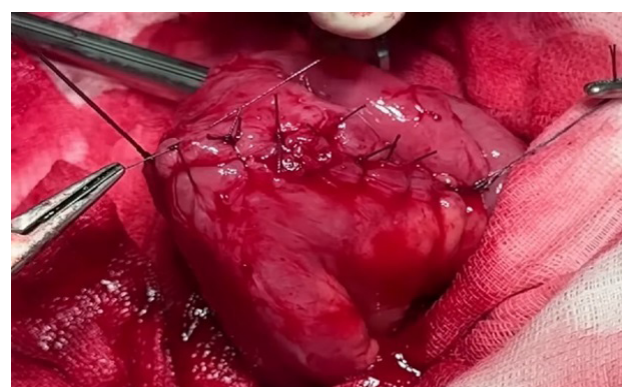


Figure 2: End to end ileal anastomosis with interrupted sutures.

Outcomes

Following surgery, patients were monitored for a full year. Mortality and morbidity rates were the main results. By documenting postoperative problems such as wound infection, intestinal obstruction, and anastomotic leakage, morbidity was evaluated. Mortality was defined as a death that happened within 30 days of the closure of an ileostomy or as a result of complications from surgery. QoL was the secondary endpoint, and it was measured at 3, 6, and 12 months after surgery using the validated EORTC QLQ-C30 questionnaire.

Statistical analysis

Version 28 of the SPSS program (IBM Co., Armonk, New York, USA) was used to analyze data. The unpaired Student's *t*-test was used to compare continuous variables, which were presented as means with SD. The χ^2 test or Fisher's exact test were used to analyse the categorical variables, which were shown as frequencies and percentages. A linear regression analysis was adopted to determine the factors influencing QoL ratings. *P* values below 0.05 were regarded as statistically significant.

RESULTS:

A total of 32 patients in all were recruited for the research and split into two equal groups at random: those who underwent early closure (14 days after surgery) and those who underwent delayed closure (2 months after surgery). 15 patients, however, were disqualified for reasons such as anastomotic leak, unstable medical conditions, or lack of follow-up. For the final analysis, 17 patients were added to each group (Figure 3).

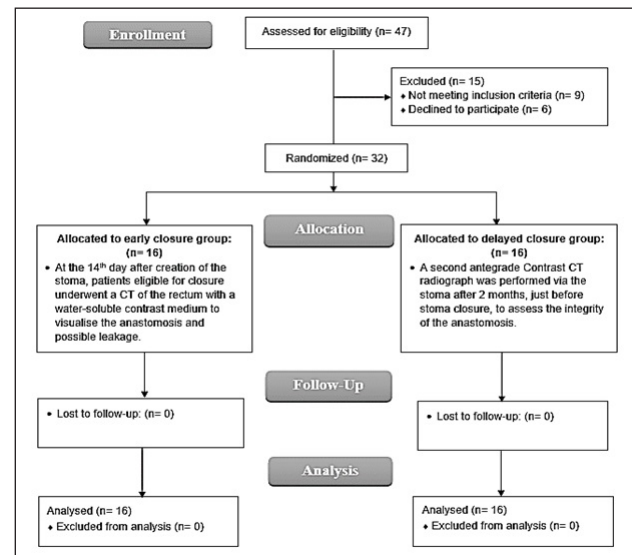


Figure 3: Diagram of study design.

Demographic factors such as age, sex, comorbidities, tumour location, and staging did not significantly varied among the early and delayed closure groups (Table 1). The distributions of these variables were comparable for the two groups.

Operative data showed comparable results between the two groups. Most patients underwent open surgery (early closure: 81.3%, delayed closure: 75%) and colorectal anastomosis (early closure: 81.3%, delayed closure: 75%). The mean operative time was similar for both groups (early closure: 130.31±25.66min, delayed closure: 127.19±23.87min) (Table 1).

Table 1: Baseline characteristics and operative data of the studied groups:

	Early closure group (n= 16)	Delayed closure group (n= 16)	<i>P</i> value
Age (years)			
Mean±SD	55.06±8.78	54.75±7.9	0.916
Range	32–66	31–63	
Sex			
Male	6(37.5)	5(31.3)	0.71
Female	10(62.5)	11(68.8)	
Comorbidities	6(37.5)	5(31.3)	0.71
Site			
Upper	3(18.8)	4(25)	>0.999
Middle	5(31.3)	5(31.3)	
Lower	8(50)	7(43.8)	
Staging			
Stage 1	1(6.3)	2(12.5)	>0.999
Stage 2	8(50%)	7(43.8)	
Stage 3	7(43.8)	7(43.8)	

	Early closure group (n= 16)	Delayed closure group (n= 16)	P value
Type of surgery			
Open	13(81.3%)	12(75%)	>0.999
Lap	3(18.8%)	4(25%)	
Type of anastomosis			
Colorectal	13(81.3)	12(75)	>0.999
Coloanal	3(18.8)	4(25)	
Operative time (min)			
Mean±SD	130.31±25.66	127.19±23.87	0.724
Range	90–180	90–170	

Data are presented as frequency (%) unless otherwise mentioned.

The groups' postoperative complications were comparable. Although the delayed closure group experienced a higher rate of preoperative skin infection (37.5%) compared with the early closure group (6.3%), the variation was not statistically significant ($P= 0.083$). The incidence of other problems, including retraction, prolapse, stenosis, and dehydration, were comparable in both groups. The incidences of enterocutaneous fistula and parastomal hernia did not change significantly. Although the early closure group had a greater risk of skin infections (18.8%) than the delayed closure group (6.3%), the difference was not statistically significant ($P= 0.6$) (Table 2).

Over the course of the 12-month follow-up period, the two groups' QoL scores were similar. The early closure group's mean score at 2 months after surgery was 102.13 ± 8.61 , but the delayed closure group's mean score

was 96.81 ± 8.77 ($P= 0.094$). At 6 months, the delayed closure group scored 102.5 ± 6.18 , while the early closure group scored 107 ± 7.38 ($P= 0.071$). At 12 months, there was no significant variation ($P= 0.462$) between the early closure group's scores of 109.56 ± 5.74 and the delayed closure group's values of 108.19 ± 4.64 (Table 3).

There were no significant predictors found in the linear regression analysis of variables linked to QoL ratings 12 months after surgery. Variables including age, sex, comorbidities, tumour site, staging, surgery type, anastomosis type, operating duration, and closure timing did not substantially affect QoL scores in either univariate or multivariable models (Table 4). In particular, the QoL score at 12 months was not significantly impacted by the timing of closure (early vs. delayed) ($P= 0.439$).

Table 2: Complications of the studied groups:

	Early closure group (n= 16)	Delayed closure group (n= 16)	P value
Preoperative skin infection	1 (6.3)	6 (37.5)	0.083
Stenosis	0	1 (6.3)	>0.999
Prolapse	1 (6.3)	2 (12.5)	>0.999
Retraction	1 (6.3)	3 (18.8)	0.6
Parastomal hernia	0	2 (12.5)	0.484
Dehydration	1 (6.3)	4 (25)	0.333
Postoperative skin infection	3 (18.8)	1 (6.3)	0.6
Enterocutaneous fistula	2 (12.5)	1 (6.3)	>0.999

Data are presented as frequency (%).

Table 3: Quality of life scores of the studied groups:

	Early closure group (n= 16)	Delayed closure group (n= 16)	P value
After 2 months			
Mean±SD	102.13±8.61	96.81±8.77	0.094
Range	80–112	75–106	
After 6 months			
Mean±SD	107±7.38	102.5±6.18	0.071
Range	94–118	83–109	
After 12 months			

	Early closure group (n= 16)	Delayed closure group (n= 16)	P value
Mean±SD	109.56±5.74	108.19±4.64	0.462
Range	99–118	96–113	

Table 4: Linear regression analysis for factors associated with quality of life score 12 months postoperatively in the studied patients:

	Univariate			Multivariable		
	Coefficient	95% CI	P value	Coefficient	95% CI	P value
Age (years)	0.06	−0.18 to 0.29	0.625	0.23	−0.22 to 0.69	0.293
Sex						
Male	Ref			Ref		
Female	0.09	−3.92–4.09	0.965	0.92	−4.39–6.24	0.72
Having comorbidities	−2.58	−6.46–1.3	0.185	−5.17	−11.03–0.69	0.081
Site						
Upper	Ref			Ref		
Middle	2.93	−2.31–8.17	0.262	3.14	−2.82–9.11	0.284
Lower	2.96	−1.91–7.83	0.223	0.44	−6.31–7.2	0.892
Staging						
Stage 1	Ref			Ref		
Stage 2	−1.73	−8.61–5.14	0.61	0.23	−11.7–12.16	0.968
Stage 3	−2.24	−9.15–4.68	0.513	−1.77	−14.27–10.73	0.771
Type of surgery						
Open	Ref			Ref		
Lap	0.53	−4.07–5.12	0.817	−2.64	−15.67–10.39	0.677
Type of anastomosis						
Colorectal	Ref			Ref		
Coloanal	2.54	−1.96–7.04	0.259	3.85	−2.66–10.37	0.232
Operative time (min)	0.02	−0.06–0.1	0.603	0.04	−0.15–0.23	0.663
Time of closure						
Early	Ref			Ref		
Delayed	−1.38	−5.14–2.39	0.462	−1.59	−5.8–2.61	0.439

DISCUSSION

The adoption of LAR with reconstruction for rectal cancer has increased markedly in recent years, thanks to improvements in surgical methods and adjunctive therapies. These developments include the creation of stapling devices, neoadjuvant chemoradiotherapy, and the increasing use of minimally invasive procedures, including robotic surgery, laparoscopic surgery, and transanal complete mesorectal excision. Despite these innovations, the rate of anastomotic leaks still ranges between 10 and 15%, with such leaks potentially leading to life-threatening complications in some cases^[2].

To mitigate the risks associated with anastomotic leaks, many rectal cancer patients undergoing surgery also undergo the creation of a covering ileostomy. According to a recent Cochrane review, this method has been demonstrated to reduce the frequency of anastomotic leaks and the requirement for emergency

reoperation^[3]. However, although covering ileostomies provide significant advantages, they also come with their own set of complications, such as skin problems, fluid and electrolyte imbalances, and parastomal hernia. Therefore, the use of covering ileostomies is typically reserved for cases where the integrity of the anastomosis is uncertain^[6].

The time of ileostomy closure varies from institution to institution and is still up for dispute. In terms of demographics, tumour stage, comorbidities, and QoL, this study compared early versus delayed closure of the ileostomy after LAR for rectal cancer.

Our analysis found no significant differences between the two groups in terms of age, sex, comorbidities, tumour location, or stage, which is consistent with the findings of Fayed *et al.*,^[7] who also found no clinical or demographic differences between

the early and delayed closure groups. In line with the findings of Farag *et al.*,^[8] there was also no discernible variation in the groups' anastomosis, operational time, or kind of surgery (open or laparoscopic)^[8].

It's interesting to note that Alves *et al.*,^[9] found that the edema and inflammation that occurred during closure contributed to the early closure group's somewhat longer mean operating time when compared with the delayed closure group. In contrast, studies by Krand *et al.*,^[10] and Lasithiotakis *et al.*,^[11] found that the delayed closure group had longer operative times due to technical challenges from fibrosis.

Although the differences were not statistically significant, Fayed *et al.*,^[7] discovered that the early closure group experienced a greater incidence of wound infections, whereas the delayed closure group experienced a higher incidence of urinary tract infections. Both groups experienced similar rates of other complications, including enterocutaneous fistulas, dehydration, and stoma-related problems. Our study observed a higher incidence of preoperative skin infections in the delayed closure group (37.5%) compared with the early closure group (6.3%), though this difference was not statistically significant, possibly due to prolonged exposure to intestinal contents in the delayed closure group.

According to Podda *et al.*'s comprehensive review and meta-analysis^[12], the total postoperative morbidity is not significantly affected by the early closure of covering ileostomies following LAR. Since there was no discernible difference in postoperative morbidity between the early and delayed closure groups, this result is in line with our findings.

We used the Gastrointestinal QoL Index (GIQLI) to assess the QoL of patients at 2, 6, and 12 months following surgery. At every follow-up point, the early closure group consistently reported somewhat higher GIQLI scores. In particular, the early closure group's mean score at 2 months was 102.13 ± 8.61 , whereas the delayed closure group's was 96.81 ± 8.77 ($P = 0.094$). The scores were 107 ± 7.38 compared with 102.5 ± 6.18 at 6 months and 109.56 ± 5.74 versus 108.19 ± 4.64 at 12 months. The results from Elgammal *et al.*,^[13] where the early closure group had a higher GIQLI score, are consistent with these differences, even if they were not statistically significant.

Similar to this, Keane *et al.*,^[14] found that while there were differences in certain domains like emotional functioning, physical pain, and mental health, with the late closure group demonstrating marginally higher scores in some areas, there were no significant differences in overall QoL scores between the early and late closure groups. According to Fayed

et al.,^[7] there was a statistically significant difference ($P = 0.027$) in the QoL scores of 85% of patients in the delayed closure group and 100% of patients in the early closure group.

Although cost-effectiveness was not a primary endpoint in our study, early closure of the ileostomy could reduce the financial burden on patients, particularly in developing countries like Egypt, by minimizing the need for multiple hospital admissions and reducing the cost of ostomy appliances.

CONCLUSION

Early closure of loop ileostomy did not substantially improve postoperative QoL compared with delayed closure in patients receiving LAR for rectal cancer. Both closure strategies had similar complication rates and surgical outcomes. Further studies of larger sample sizes are needed to confirm these findings. However, early closure is highly recommended due to the financial burden of bag cost of colostomy bags. In addition, the psychological outcomes of patients who had early closure were better than others. Therefore, early closure is recommended.

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Declarations section: Ethics approval and consent to participate: Before the commencement of the study, each participant completed a written consent that was authorized by Menoufia Faculty of Medicine's local Ethical Research Committee. Additionally, the Institutional Review Board was obtained [-----].

Availability of data and materials: The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

AUTHORS' CONTRIBUTIONS

M.A.E. revised the results and shared in manuscript writing and editing. A.A.E. established the concept of the study and analyzed data. A.A.A. constructed the idea, shared in interpreting the results, and revised the manuscript. S.S.I. provided the study design and conducted data analysis. A.S.M. applied clinical studies, collected data, and shared in writing the manuscript. M.A.E. collected data, analyzed results, and prepared manuscript. All authors read, revised and approved the final manuscript.

CONFLICT OF INTEREST

There are no conflicts of interest.

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